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10/518,427	09/30/2005	Andrew David Miller	CU-4022 RJS	6762

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EXAMINER
LAO, MARIALOUISA

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1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,427	MILLER ET AL.	
	Examiner	Art Unit	
	M. Louisa Lao	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Lack of Unity

1. Applicants' election of the species for Group A, Group B and Group C in the reply filed on 4/9/07 is acknowledged. The traversal is on the ground(s) that the claims, as amended, now recite the special technical feature that unites the groups.

2. Having taken Applicants' arguments and amendments into advisement, the lack of unity raised is obviated and the claims are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 108-112 and 115 are rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Claims 108-112 and 115 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of lowering concentration of cholesterol and triglycerides in the blood of mammals comprising administering to said subject an effective amount of a compound of Formula I, as recited, does not reasonably provide enablement for a) method for inhibiting the oxidative modification of low density lipoprotein, b) a method for producing weight loss or a reduction of the fat mass in a human or non-human animal in need thereof, c) a method for the modification of the fat distribution and content of animals, d) a

method of *inhibiting or preventing* the growth of tumors, e) a method for the treatment or *inhibition* of primary and secondary metastatic neoplasms, f) a method for the prevention or treatment of proliferative skin disorders, g) a method for the *inhibition* of proliferation or induction of differentiation of keratinocytes, h) a method for the *prevention* or treatment of inflammatory disorders, i) a method for enhancing the endogenous production of interleukin-10 in mammalian cells or tissues, j) a method for suppression of the endogenous production of interleukin-2, k) a method for the inhibition of proliferation of stimulated peripheral mononuclear cells. The specification does not enable the person skilled in the art, to make the invention commensurate in scope with these claims. The factors to be considered in making an enablement rejection have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in the art, g) the predictability or unpredictability of the art, and, h) the breadth of the claims.

6. In the present case, the important factors leading to a conclusion of undue experimentation are the absence of any working example of the aforementioned methods (a-k), the lack of predictability in the art, the amount of direction and guidance provided and the broad scope of the claim.

a) the amount of experimentation needed. Since the compounds of Formula I are replete with substituents effectuating to different structures with invariable distinct characteristics, the quantity of experiments corresponding to the method of treatment for the recited disorders thereto, would likewise be numerous.

b) the amount of direction and guidance provided. The specification on page 65-78 recites the experiments using Wistar rats and the evaluations performed, including *inter alia* lipid lowering effects, fatty acid oxidation, activity of mitochondrian enzymes, carnitine palmitoyltransferase-II.

c) the presence or absence of working examples. There are no working examples of methods (a-k) for inhibition or prevention of disorders, illustratively of primary and secondary metastatic neoplasms, proliferative skin disorders. The various examples presented are found deficient to encompass the plurality of disorders and the population of humans and animals with said disorders.

d) the nature of the invention and the e) the state of the prior art. Methods using phospholipid compounds of similar structure as recited in Formula (I) are known, see Jamila et al. (US2004192908, US`908 *in IDS*).

f) the relative skill of those in the art. The skilled artisans are synthetic organic chemists and clinical pharmacists with graduate degrees and potentially with many years of research and industrial experience.

g) the predictability or unpredictability of the art. The state of the art of method of treatment is unpredictable, since this art is largely empirical, which requires fulfilling a rationale for the optimization of absorption, distribution, metabolism, and excretion of a drug. Determining whether a compound meets the attributes of a useful prodrug entails substantial clinical testing with laborious experimentation. See Goodman & Gilman's *The Pharmacological Basis of Therapeutics"*. 10th ed. NY McGraw Hill 2001 p3.

h) the breadth of the claim. Claims 108-112 and 115 recite methods (a-k), as discussed *supra* comprising administering to said subject an effective amount of a compound of Formula I. This is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/use the full scope of the claimed invention without undue experimentation. In re Wright 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed.Cir.1993)." That conclusion is clearly justified here: Thus, undue experimentation will be required to practice Applicants' invention.

Provisional Obviousness Double Patenting Rejection

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. **Claims 61-119 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over *claims 1,9,13,20-23,32,33,39-44 and 48 of copending Application No. 10/484855 (US2004/0219202).* Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant lipid compound

of formula (I) is the same as the copending application's lipid compound when the instant substituents of formula (I) match. Illustratively, when X=C_6-C_{24} containing one or more double bonds; Y= O or CH_2, Z=$C_{1\text{-}10}$ alkyl group; PHG=polar head group and the use of said lipid compound for the treatment of a disorder.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. **Claims 101 and 116-119 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 and 37-41 of copending Application No. 10/550129 (US2007/009608) or claims 143 and154 of copending Application No. 10/550033 (US2007/0015795).

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant composition comprising the lipid compound of formula (I) is recited in the copending applications 10/550129 and 10/550033, when the substituents of lipid compound in the latter copending applications match the substituents of the instant lipid compounds' substituents. Illustratively, when the phospholipids and X groups match.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Provisional Rejection Under 102(e)/103

10. **Claims 61-119 are provisionally rejected** under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/484855 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it

would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant lipid compound of formula (I) is the same as the copending application's lipid compound when the instant substituents of formula (I) match. Illustratively, when X= C_6-C_{24} containing one or more double bonds; Y= O or CH_2, Z=C_{1-10} alkyl group; PHG =polar head group and the use of said lipid compound for the treatment of a disorder.

11. This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

12. **Claims 101 and 116-119 are provisionally rejected** under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/550129 (US2007/009608) or copending Application No. 10/550033 (US2007/0015795) which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending applications, these would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. Although the conflicting claims are not identical, they are not patentably

distinct from each other because composition comprising the instant lipid compound of formula (I) is the same as the copending applications' lipid compound when the instant substituents of formula (I) match. Illustratively, when PHG=polar head group matches the phospholipid non-ß oxidizable entity.

13. This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Rejection Under 102(f)/103 or 102(g)/103

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. **Claims 61-119 are rejected** under 35 U.S.C. 102(g)/103(a) as being unpatentable over Fletcher et al. (US2004/0219202, US`202).

Applicant Claims

19. The instant claims are drawn to a lipid compound of formula (I) $(XYZ\text{-}C{=}O)_p$-PHG with substituents as defined therein, a combination of a liposome and a compound of formula (I), a method for the production of a lipid compound of formula (I), a cosmetic formulation comprising a lipid compound of formula (I), a method of making the compound of formula (I), a pharmaceutical composition comprising a compound of formula (I) and a method of treating a plurality of disorders selected from, *inter alia,* Syndrome X, obesity, comprising administering to a subject in need thereof an effective amount of a compound of formula (I) or a pharmaceutically acceptable salt thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

20. US`202 teaches a composition comprising a lipid compound comprising at least one non-polar moiety and a polar moiety, where the formula of the compound is recited and the substituents thereto; a lipid compound of the formula $(XYZ\text{-}C{=}O)_p\text{-}PHG$ and the substituents defined thereto, a liposome comprising the compound of the formula as recited, the method of preparing a medicament using the recited lipid compound, a pharmaceutical composition comprising said lipid compound and the use of said lipid compound and said liposome in the manufacture of a medicament for the treatment of *inter alia,* a disorder.

Ascertainment of the Difference Between Scope of the Prior Art and the Claims (MPEP §2141.012)

21. US`202 does not expressly disclose or suggest the method of making a cationic liposome from a lipid compound comprising at least one non-polar moiety and a polar moiety and the substituents, as described therein.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

22. One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to start with the teachings of the cited prior art reference to make a lipid compound, a liposome and suitable formulations and the corresponding medicaments to treat a plurality of disorders, to make applicants' lipid compound, using said methodology. The teachings of the cited prior art suggest that specific features of the invention may be combined with other features in accordance with the invention, and alternatively embodiments will be recognized by those skilled in the art and are intended to be included within the scope of the claims. Therefore, it would have been obvious to modify the cited prior art, to make the instant lipid compound and instant formulations incorporating said compound and the uses thereto

since said lipid compound, formulations and uses have been taught and are within the purview of artisan to adapt the use of compounds discovered in his art to develop a more economical process with a reasonable expectation of success.

Optimizing such processes is *prima facie* obvious because an ordinary artisan would be motivated to use known processes from the art to make the process more efficient or explore economical advantages over the other. Merely modifying the process conditions is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

23. **Claims 101 and 116-119 are rejected** under 35 U.S.C. 102(g)/103(a) as being unpatentable over Berge (WO2006/009464, WO`464 equivalent to US2007/009608) or Berge (WO2006/00946, WO`946 equivalent to US2007/0015795).

Applicant Claims

24. The instant claims are drawn to a pharmaceutical composition comprising a compound of formula (I) $(XYZ\text{-}C{=}O)_p\text{-}PHG$ with substituents as defined therein and admixed with a pharmaceutically acceptable carrier, diluent, excipient or adjuvant, which can be administered topically, parenterally and intravenously.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

25. WO`464 teaches in claims 27 and 37-41 a composition comprising a combination of a plant oil and/or fish oil; and one or more compounds comprising non ß-oxidizable fatty acid entities represented by a formula as recited therein, wherein the compound comprising a non ß-oxidizable fatty acid entity is a phospholipid, with various selections thereto, X= sulphur or selenium.

Ascertainment of the Difference
Between Scope of the Prior Art and the Claims

(MPEP §2141.012)

26. WO`464 does not expressly disclose a composition comprising, *inter alia,* a lipid compound comprising at least one non-polar moiety and a polar moiety and the substituents, as described therein, nor the various modes of administration thereto.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

27. One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to start with the teachings of the cited prior art reference(s) to make a suitable composition using the instant lipid compound. The teachings of the cited prior art suggest that specific features of the invention may be combined with other features in accordance with the invention, and alternatively embodiments will be recognized by those skilled in the art and are intended to be included within the scope of the claims. Therefore, it would have been obvious to modify the cited prior art, to make the instant composition comprising the lipid compound since said lipid compound have been taught and are within the purview of artisan to adapt the use of compounds discovered in his art with a reasonable expectation of success.

Optimizing such processes is *prima facie* obvious because an ordinary artisan would be motivated to use known compounds from the art to make combinations that are more efficient or explore economical advantages over the other. Merely modifying the combinations is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

28. **Claims 101 and 116-119** directed to an invention not patentably distinct from claims 27 and 37-41 of commonly assigned US2007/009608 or US2007/0015795. Specifically, a composition comprising a combination of a plant oil and/or fish oil; and one or more compounds comprising non ß-oxidizable fatty acid entities represented by a formula as recited therein,

wherein the compound comprising a non ß-oxidizable fatty acid entity is a phospholipid, with various selections thereto, X= sulphur or selenium.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned applications, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Provisional Rejection of Later Application under 102(e)/103

29. **Claims 101 and 116-119 are** provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/550033 and 10/550129 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

30. This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Fridays from 8:30am to 5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

`mll 06262007
MLouisa Lao
Examiner
Art Unit 1621

for YVONNE EYLER
SUPERVISORY PATENT EXAMINER
TC1600 GAU 1621